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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/697,121	10/27/2000	Tatsuro Kawamura	43888-087	6319

7590

08/13/2003

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EXAMINER

SIEFKE, SAMUEL P

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 08/13/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/697,121

Applicant(s)

KAWAMURA, TATSURU

Examiner

Samuel P Siefke

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 22 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 and 9-12 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 9 and 12 is/are allowed.
- 6) ☒ Claim(s) 1,3-5,10 and 11 is/are rejected.
- 7) ☐ Claim(s) 2 and 6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of claims 7 and 8 in Paper No. 6 is acknowledged.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Sawai et al. (USPN 4,203,724).

Sawai discloses a method for the measurement of antigens or antibody or a mixture thereof with the corresponding antibody and/or antigen that comprises measuring a transmitted light and scattered light intensities of a solution to be detected containing antigens and antibody components before, during, and after mixing a reagent (corresponding antibody and/or antigen), which changes the optical characteristics of the solution to be detected attributed to the specific component of interest (col. 3, lines 18-32; col. 4, line 66- col. 5, line 14; col. 5, line 59-68); comparing the measured values against the known values to detect false measurement due to unwanted particle suspended in the solution (base line vs. known concentration measurements col.3, lines 57-68).

***Allowable Subject Matter***

Claims **9** and **12** are allowed.

Claims **2** and **6** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 2 would be allowable because the prior art does not teach or fairly suggest the low concentration of a substances be determined based solely on the scattered light intensities and the high concentration of the substances be determined solely on the transmitted light intensities before and after the mixing of the reagent. Claim 9 is allowable for the same reasons as claim 2. Claim 6 would be allowable because the prior art does not teach or suggest determining the concentration of an optically active substance based on optical rotation and then determining the concentration of the optically active substance other than the protein from the protein concentration and optical rotation. Claim 12 is allowable for the same reasons as claim 6.

***Response to Arguments***

Applicant's arguments filed 5/22/03 have been fully considered but they are not persuasive. Applicant argues that the step of measuring the transmitted light intensities before mixing the reagent is not supported in Sawai. Sawai uses a calibration curve fig. 4 of change of percent absorption with time at various concentrations of hCG solutions. The first measurement without any hCG solution would be the before measurement

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because every measurement taken after would be compared to this baseline in order to determine if the spectrophotometer is "zeroed in" or calibrated so that proper measurements can be taken and relied on as being precise and free of any unwanted background (see fig. 4 at 0 percent absorption and 0 time).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P Siefke whose telephone number is 703-306-0093. The examiner can normally be reached on M-F 7:00am-5:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers

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for the organization where this application or proceeding is assigned are 703-872-9311 for regular communications and 703-872-9310 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

SPS  
August 7, 2003



Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700